

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: _____

Ian D. McRury et al.

Confirmation No. 3998

Application No. 10/024,625

Art Unit: 3731

Filed: December 18, 2001

Examiner: Darwin P. Erez

For: SUTURE WELDING SYSTEM AND METHOD

Mail Stop After Final
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

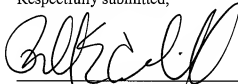
PRE-APPEAL BRIEF REQUEST FOR REVIEW

Dear Sir:

In response to the Final Office Action dated January 4, 2007, Applicants request a pre-appeal brief review. No amendments are being filed with this request. This request is being filed with a notice of appeal. This review is requested for the reasons stated in the attached sheets.

Dated: June 4, 2007

Respectfully submitted,



Ronald B. Cahill, Reg. No. 38,403
Attorney For Applicants
NUTTER MCCLENNEN & FISH, LLP
World Trade Center West
155 Seaport Boulevard
Boston, Massachusetts 02210-2604
Tel. (617) 439-2782
Fax (617) 310-9782

REASONS FOR THE REQUESTED REVIEW**Introduction**

The invention claimed herein relates generally to suture welding systems and methods where a device for grasping sutures is provided with two electrodes connected to a source of electrosurgical energy so that the electrosurgical energy, generally radio frequency energy, can be passed through the sutures to weld them together. There are no references cited that provide electrodes connected to a source of electrosurgical energy to provide radio frequency energy to the sutures to weld them.

Background of the Art

The Fenton reference cited by the Examiner as the primary reference relates to the ultrasonic fusing of a fusible collar that is placed around two lengths of suture. Fenton is assigned on its face to Axya Medical, Inc. ("Axya"). Throughout prosecution of the present application, a number of Axya references have been applied – all deal with ultrasonic welding. Some of these references (see, e.g., the previously cited US 6,358,271 to Egan et al.) actually weld suture material directly, however, none of these are presently cited as none of them mention electrosurgical, or RF, energy as the welding tool. Fenton, on the other hand, is distinguished over the other Axya references by virtue of its fusible collar – in fact, the collar is recited in every claim. The reason for relying on this reference, as opposed to the other "direct" welding references is that the Fenton reference actually does mention electrical or RF energy, which the Examiner uses as a reason to combine Hulka. Fenton, however, only applies ultrasonic energy (or the laundry list of other types of energy sources) to the fusible collar, which is specially formed for the purpose of fusing. There is no teaching or suggesting of applying the Fenton technique directly to sutures (which are not formed for the purpose of fusing, but for holding tissue). Indeed, there are no references that apply RF energy to welding – all of the RF references resemble the Hulka reference cited by the Examiner – using RF for cutting and cauterizing of tissue, not for welding sutures.

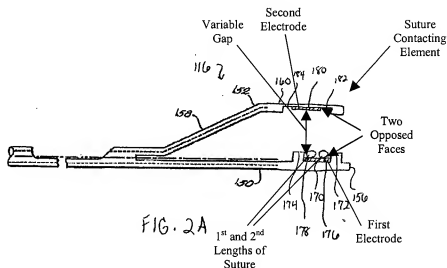
Rejection of Claims 1, 3-7, 20, 21, and 23-34 Under 35 U.S.C. 103(a)

The Examiner states that claims 1, 3-7, 20, 21, and 23-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 6,409,743 (Fenton, Jr.) in view of U.S. 6,010,516 (Hulka). Fenton, the primary reference, relates to ultrasonic welding. Hulka provides a "coaptation clamp" device that delivers RF energy only to tissue and does not relate to sutures.

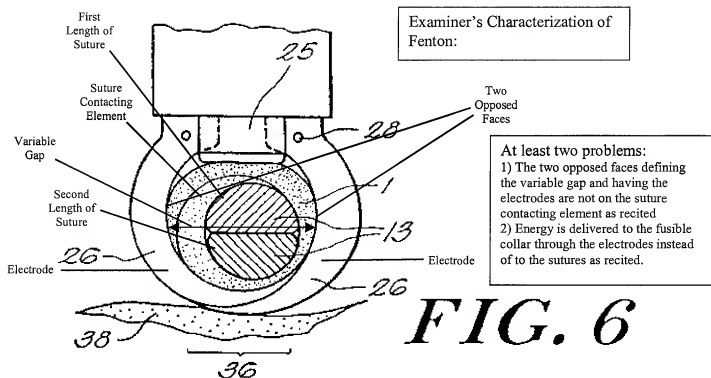
Fenton teaches a “fusible collar for securing sutures without knots and for securing living tissue structures together without sutures.” [See Abstract.] **Every embodiment** disclosed in Fenton includes this fusible collar, every claim in Fenton recites this fusible collar, and the invention in Fenton is expressly described as residing in the collar. The presently claimed invention works differently. [See, for example, pages 9 to 11 of Applicant’s March 5, 2007 Amendment and Response Pursuant to 37 C.F.R. §1.116.]

Differences from Primary Reference – Using Method Claim 20 as an Example

In this claim, a suture welding device is provided with a ***suture contacting element having two opposing faces having a variable gap therebetween, with each face having an electrode*** disposed thereon. First and second lengths of suture are disposed in contact with the ***suture contacting element*** and ***electrosurgical energy is provided “through the first electrode to the first and second lengths of suture to weld the first length of suture to the second length of suture.”*** Using Figure 2A as an illustrative embodiment to see these features in application:



Fenton, which works differently, does not disclose, teach or suggest the structure or action recited in method claim 20. In Fenton, welding horn (25) melts the fusible collar (1) to bind the sutures together.



According to the Examiner, jaws (26) are the “working end” of claim 20, while fusible collar (1) is the suture contacting element. According to the Examiner, the “variable gap,” (and thus necessarily the “two opposed faces”) are provided by adjustable jaws (26). The Examiner modifies these jaws (26) to be “electrodes.”

While Fenton as characterized and modified by the Examiner may include the elements of the claim – those elements are not configured or used (and claim 20 is a method claim) as recited. For example, Claim 20 recites that it is the suture contacting element (the fusible collar (1) in Fenton) that must have two opposing faces that define a variable gap therebetween. The Examiner puts those features on the working end (jaws (26) in Fenton), as he must, instead of on the suture contacting element (fusible collar (1)) as recited in the claim. Similarly, the claim recites that the electrodes are on the two opposed faces on the suture contacting element. In the Examiner's modification, the electrodes are on the opposing faces on the working end instead of on the suture contacting element as recited.

Fenton has a different structure because it delivers ultrasonic energy to a fusible collar – not electrosurgical (or RF) energy to sutures to weld them together. Accordingly, there is no

way to put the structures of Fenton together, even if one added electrodes to them, so that the electrodes deliver energy to the sutures to weld them together.

There is No Suggestion or Motivation to Put Electrodes on Suture Contacting Element

The Examiner further asserts that Applicants' arguments regarding the fact that Fenton fails to teach the application of RF energy to weld sutures (as opposed to teaching ultrasonic energy to melt the fusible collar) are not persuasive because:

Furthermore, the collar/suture contacting element is able to fuse suture together without the collar fusing along with the suture, as stated in col. 7, lines 3-11. [Advisory Action.]

First, the passage cited by the Examiner relates to ultrasonic welding. Second, this passage merely states that the collar and sutures can be made from materials with different melting points to allow the bonds to occur at various interfaces. Neither this passage, nor any other passage of Fenton, says that energy can be added to the sutures to weld them together – rather, Fenton says that the techniques can be applied to collars – not to sutures.

The actual passages from Fenton that discuss RF energy are as follows:

The overlapping portions of the collar are adapted to fuse to each other around the elongated members upon ***application of sufficient energy to the overlapping portions of the collar.*** . . . The energy may be generated from a variety of sources known in the art, such as for example, thermal energy, optical energy, radio-frequency energy, current sources or more preferably, ultrasonic energy. [Column 2, lines 15-39.]

Various methods of fusing or joining sutures or other elongated structures together ***joining by the application of energy to the fusible collar are well known in the art and can be employed to secure the band and sutures.*** Examples of such techniques include, but are not limited to, thermal energy (e.g., heat), optical energy (e.g. laser), electrical (e.g., radiofrequency RF), current sources (e.g., resistive heating), and preferably, ultrasonic energy. [Column 4, lines 43-51.]

The collar material ***is preferably also capable of being fused or joined together upon the application of energy,*** such as thermal energy (heat), optical energy (laser generated), electrical energy (radio frequency, RF), current sources (resistive heating) or, preferably, ultrasonic energy, to the collar. [Column 6, lines 36-39.]

In each case, Fenton only talks about applying energy to the collar – never to the suture as is required by the present claims. There is no suggestion to apply RF energy to the sutures, and no reason to believe that such an application would work. As noted above (in the “Background of the Art”), previously cited ultrasonic welding patents apply energy to sutures, but conspicuously do not reference RF energy. Cited RF energy references relate only to cutting

and cauterizing of tissue. Fenton makes the leap of referring to RF in the context of “welding” – but only by application to a fusible collar that is specifically designed for that purpose. There is no suggestion or motivation to apply RF energy to the sutures to weld them – and there is no reason to believe that it would work.

Claim 1 is Patentable for the Same Reasons

Claim 1 recites, *inter alia*, first and second lengths of suture and a suture welding device including a **suture contacting element having the first and second lengths of suture disposed thereon**. A **first electrode** is disposed on the suture contacting element **for providing radio frequency energy to the first and second lengths of suture**. Again, the first and second lengths of suture are positively recited as being disposed on the suture contacting element (which the Examiner analogizes to the fusible collar) – but the electrode is also provided on the suture contacting element to provide radio frequency energy to the first and second lengths of suture. The fusible collar of Fenton does not provide such an electrode – nor would a person of ordinary skill in the art so place the electrode on a meltable object.

The Hulka Reference Fills In None of the Missing Teachings

Hulka does not teach or suggest these claim recitations. Hulka, which provides a coaptation clamp device delivers RF energy only to tissue as is well known and as been recognized in numerous patents cited in the prosecution of the present application. No portion of the Hulka device contacts sutures, sutures are never disposed on the device, and RF energy is not delivered to sutures. Accordingly, neither reference, alone or combined, teaches or suggests the recitations of the claims.

Claims Relating to Polydioxanone Sutures Are Further Patentable

Even further, Applicants’ claims 6, 26 and 34 recite first and second lengths of suture that are made of polydioxanone. Just because polydioxanone sutures are known does not mean that they can be welded as recited in the claims. In fact, an express goal of the claimed invention, the first suture welding device of its type, is to employ radio frequency waves in order to facilitate the welding of polydioxanone sutures as the present inventors have found that existing suture welding methods did **not** work with polydioxanone sutures. (See, e.g., the background of the present invention at page 1, lines 22 to 31.) Fenton’s approach does not change these facts because Fenton does not weld the sutures, he heats a fusible collar as a substitute.